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PATENT Customer No. 22,852 Attorney Docket No. 1147.0142

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of: U.S. Patent No. 5,750,338)
Mark L. Collins et al.) Group Art Unit: 1655
Reissue Serial No.: 09/533,906) Examiner: D. JOHANNSEN
Filed: March 8, 2000	j
TARGET AND BACKGROUND CAPTURE	\(\)
METHODS WITH AMPLIFICATION FOR	<u> </u>
AFFINITY ASSAYS)

REISSUE LITIGATION BOX

Commissioner for Patents Washington, DC 20231

Sir:

UPDATED NOTICE OF RELATED LITIGATION

Further to the Patent Owner's submission of February 21, 2002, the Patent Owner brings to the attention of the Office the following papers reflecting the current state of the case following a jury verdict rendered on May 22, 2002:

- Transcript of Jury Verdict, May 22, 2002 ("Transcript");
- Judgment for Gen-Probe on its Declaratory Action of Non-infringement and Invalidity; and
- Order (1) Denying Gen-Probe's and Vysis's Pre-Verdict Motions for Judgment as a Matter of Law, and (2) Setting Briefing Schedule for Post-Trial Motions ("Order").

The jury rendered a verdict that the original patent claims were not infringed and were invalid for obviousness and lack of enablement. The jury rendered "advisory" verdicts that the

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1300 I Street, NW Washington, DC 20005 202.406.4000 Fax 202.408.4400 www.finnegan.com claims had been inequitably procured and were unenforceable for prosecution laches. Vysis believes that the jury verdict was incorrect and has moved for judgment as a matter of law and for a new trial.

To put these papers in context requires a brief explanation. In any jury trial, certain issues are decided by the jury and certain others are reserved for the court. Specifically, traditional "legal" issues are decided by the jury, while "equitable" issues are decided by the court. In patent litigation, infringement and the affirmative defense of invalidity are legal issues (provided damages are sought) and thus, are decided by a jury. See TegalCorp. v. Tokyo Electron America, Inc., 257 F.3d 1331, 1341, 59 U.S.P.Q.2d 1385, 1391 (Fed. Cir. 2001). In contrast, inequitable conduct is an equitable issue and as such is reserved for the court to decide. See Paragon Podiatry Laboratory v. KLM Laboratories, 984 F.2d 1182, 1190, U.S.P.Q.2d 1561, 1568 (Fed. Cir. 1993). The judge may submit an equitable issue, such as inequitable conduct, to the jury for an "advisory verdict," as the court did in this case. See FED. R. CIV. P. 39(c). However, an advisory verdict has no binding effect on the court, but only provides guidance. See Carbide Blast Joints, Inc. v. Vermont American Corp., 1995 U.S. App. LEXIS 33800 at 9-11 (Fed. Cir. 1995); Hamm v. Nasatka Barriers, Inc., 166 F.R.D. 1, U.S. Dist. LEXIS 3445 (D.D.C. 1996) ("An advisory verdict has no force, other than persuasive, on the court, which remains the sole and final decision-maker."). Thus, the court still must undertake its own separate analysis of the inequitable conduct issues, and the Transcript notes at page 1784, lines 24-25, the court's view that "I think Gen-Probe is going to have the laboring oar on that."

The substance of the allegations upon which the jury verdict was based have already been made of record through the Patent Owner's prior Notices of Related Litigation. The judgments entered on non-infringement and invalidity are not yet final, appealable judgments under Rule

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1300 I Street, NW Washington, DC 20005 202.408.4000 Fax 202.408.4400 www.finnegan.com 54(b), Fed. R. Civ. P., because there remain other claims in the case upon which judgment has not been entered. Moreover, as set forth in the Order, the court set a briefing schedule for Vysis's motions for judgment as a matter of law under Rule 50, Fed. R. Civ. P., and for a new trial under Rule 59, Fed. R. Civ. P. Only after those motions are ruled upon and judgment is entered on all claims in the case will any judgment be ripe for appeal. Rule 4(a)(4)(A), Fed. R. App. P. Accordingly, the Patent Owner believes that the events reflected in the papers submitted with this Updated Notice should not affect reissuance of this patent. See, e.g., Interconnect Planning Corporation v. Feil, 774 F.2d 1132, 1135-36, 227 U.S.P.Q. 543, 545-46 (Fed. Cir. 1985) (no collateral estoppel affect on reissue where judgment on original patent has not been reviewed on appeal).

If there is any fee due in connection with the filing of this Notice, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

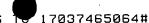
Date: June 11, 2002

Jean Burke Fordis Reg. No. 32,984

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Page 1780
                   IN THE UNITED STATES DISTRICT COURT
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                 FOR THE SOUTHERN DISTRICT OF CALIFORNIA
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                                           Civil Action
     GEN-PROBE INCORPORATED,
                                           NO. 99CV2668-H
 4
                                           San Diego, California
           Plaintiff,
                                           May 22, 2002
 5
                                           4:30 p.m.
           v.
 6
                                           JURY TRIAL
     VYSIS, INC.,
 7
                                          VOLUME X
          Defendant.
 8
                                           Pages 1780-1787
 9
                            DAILY COPY
10
                   REPORTER'S TRANSCRIPT OF PROCEEDINGS
 U
11 12 13 14 15 16
                  THE HONORABLE MARILYN L. HUFF, PRESIDING
     APPEARANCES:
     For the Plaintiff:
                                     STEPHEN P. SWINTON, ESQ.
                                     J. CHRISTOPHER JACZKO, ESQ.
                                     COOLEY GODWARD
                                     4401 Eastgate Mall
                                     San Diego, CA 92121
     For the Defendant:
                                     CHARLES E. LIPSEY, ESQ.
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N
                                     THOMAS W. BANKS, ESQ.
                                     L. SCOTT BURWELL, ESQ.
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21
                                     Linda S. Nelson, RMR, CRR
     Reported by:
22
                                     Official Court Reporter
                                     940 Front Street, Box 18
                                     San Diego, CA 92101
23
                                     Telephone: (619) 696-7559
24
                  Proceedings reported in stenotype.
         Transcript prepared by Computer-Aided Transcription.
25
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Page 1781 Page 1783 PROCEEDINGS that Vysis misrepresented or failed to disclose material facts 1 (In session at 4:30 p.m.) to the United States Patent and Trademark Office ("PTO") with 2 THE COURT: It is so empty here without all the 3 the intent to deceive the PTO? 3 4 Yes 4 boxes. I'm informed that the jury has a verdict. 5 Has Gen-Probe proved by clear and convincing evidence 5 THE CLERK: Number 1 on calendar, 99CV2668, Gen-Probe that Vysis deliberately and unreasonably delayed the 6 б Incorporated v. Vysis, Inc., on for jury trial, tenth day. 7 prosecution of the '338 patent? 7 8 8 JUROR: Same spots? 9 The foreperson should sign and date this document. The 9 THE COURT: Same spots. (Jury present) 10 date is 5-22-02 and the foreperson is -10 THE COURT: Now, logistically, do you have the phone 11 THE COURT: Name? 11 number we could call for you and say that --12 JUROR: Matthew Dicori, 12 13 JUROR: Yeah. Can you do that for me? 13 THE CLERK: Ladies and gentlemen of the jury, is this verdict, as presented and read, the verdict of each of you, so 14 THE COURT: Sure. 14 JUROR: 619-925-7083. Supposed to meet her like right 15 say you all? 15 JURORS: (Collective affirmation). now out in front. 16 16 THE COURT: Members of the jury, have you reached a 17 THE COURT: Would you like the jury polled? 17 18 verdict? Do you want to hand the verdict to my bailiff? 18 MR. LIPSEY: No, Your Honor, we're content. 19 THE CLERK: United States District Court, Southern 19 THE COURT: All right. Thank you. Well, you have 20 District of California. Gen-Probe Incorporated, Plaintiff, v. 20 finished your job and now there is some additional work that 21, Vysis, Inc., Defendant, case number 99CV2668-H(A)B), SPECIAL 21 the Court will have to do with the parties. I did say at the 22 VERDICT. beginning that I thought you would find that it is a very نينيا 23 A. INFRINGEMENT 23 interesting case, and this is really the - just the beginning 1. Has Vysis, Inc. ("Vysis") proved by a preponderance of 24 of the technology in this area. And we're going to hear a lot 25 the evidence that Gen-Probe Incorporated ("Gen-Probe") more about all the biotechnology as the matters are invented Ш Ų, Page 1782 Page 1784 1 infringes the '338 patent under the doctrine of equivalents? and discovered. It is a fascinating case, and I did think that both jobs did a wonderful job in the presentation. 2.≊ 2. Identify any claims of the '338 patent that Vysis has 3 You're free from your admonition. You're free to talk to 4 proved are infringed under the doctrine of equivalents. 4 the parties about the case. Whatever you say may be used for No claim is marked. 5 purposes of appeal. It may be put into a declaration form. 6 **B. INVALIDITY** You're not required to talk to them, if you don't want to. 7 You should check out with the jury room first. And then, 3. Has Gen-Probe proved by clear and convincing evidence 8 that any or all of the claims of the '338 patent are invalid on 8 if the parties want to talk to you, then you can talk to them 9 The ground of obviousness? outside the jury room because they need to go check out. 10 10 I do want to thank you for all the time and attention that 11 4. Identify any claims of the '338 patent that Gen-Probe 11 you've given to this court. You're free to go. 12 has proved are invalid on the ground of obviousness. 12 THE CLERK: Yes, they can go downstairs. 13 13 THE COURT: The notebooks are - you can take that, if 5. Has Gen-Probe proved by clear and convincing evidence 14 you want, the patent notebook. 15 that any or all of the claims of the '338 patent are invalid on 15 (Jurors dismissed) 16 the ground of lack of enablement? 16 THE COURT: If you wish, you can go downstairs and 17 17 talk to them and then come back, if you want to do that. No? 18 6. Identify any claims of the '338 patent that Gen-Probe 18 MR. LIPSEY: I would just as soon get our business 19 has proved are invalid on the ground of lack of enablement. 19 straight here, if it's all right with you. I don't know how 20 All. Mr. Swinton feels. 20 21 7. Has Gen-Probe proved by clear and convincing evidence 21 MR. SWINTON: That would be my preference. I have one 22 that Vysis abandoned the invention claimed in the '338 patent? 22 of my colleagues down there. 23 23 THE COURT: All right. The Court said that it would 24 C. EQUITABLE CONDUCT 24 set a briefing schedule. And on the inequitable conduct, I 25 8. Has Gen-Probe proved by clear and convincing evidence think Gen-Probe is going to have the laboring oar on that. I,

Page 1787 Page 1785 frankly, thought that Vysis had a pretty good chance at getting CERTIFICATE an answer yes to question number 1. I, Linda S. Nelson, Official Court Reporter for the So each of you have filed motions. My law clerk will send 3 Southern District of California, do hereby certify: you out a briefing schedule. Is that fine? 4 That the foregoing is a true and correct transcript of the proceedings had in the above-entitled action; that I reported MR. LIPSEY: If I might plead, I guess, there is a lot 5 same in stenotype, being the duly appointed, qualified and here abviously. If the Court could be generous in the time to 6 acting official court reporter, to the best of my ability; and give us time to deal with it, we would certainly appreciate 7 thereafter transcribed same into typewriting through 8 that. Computer-Aided Transcription. THE COURT: All right. Well, how much time are you 7 9 Date: May 22, 2002 thinking? Because we have a change in law clerks and a 10 8 Linda S. Nelson, RMR, CRR conflict with the next law clerk coming in on this issue. It Official Court Reporter really does need to be over and done with by mid August 12 9 completely. 10 13 11 14 MR. LIPSEY: I would like to formally move for JMOL 12 and also for a new trial. Plus, if there are any questions, 15 13 that we have timely done it. 16 14 THE COURT: Yes. 17 15 16 MR. LIPSEY: And in terms of the briefing schedule, 18 17 for getting papers in on that, if we could have four weeks on 19 18 that, I think that would be ample for us to recover and to get 19 21 the papers in. And I would hope -20 22 21 THE COURT: We'll consider that and then send out a 22 23 briefing schedule that will get it all done. But we really do 23 24 need to have it all finished and wrapped up, and that should 24 25 give everybody plenty of time to do that. 25 Page 1786 ı MR. LIPSEY: Thank you. 2≋ THE COURT: All right. Thank you. Anything else? 3□ MR. SWINTON: Nothing for our side. THE COURT: All right. Thank you. I do want to 5 compliment the parties. It has been a pleasure to have you in 6 my court. MR. LIPSEY: We would like to thank the court and, particularly, the court staff, who has been very accommodating 9 to us. We very much appreciate it. 10 MR. SWINTON: We do. Thank you. THE COURT: As an aside, I do think that the reissue 11 is alive and well and so we may see you back and probably we'll 12 see you back. And obviously there is a number of issues that remain to be litigated under the special verdict. It puts both things in play again. 16 MR. SWINTON: Thank you, Your Honor. 17 THE COURT: All right. Thank you. THE CLERK: We're in recess. 18 19 (Proceedings concluded at 4:40 p.m.) 20 21 22 23 24 25

FILED 02 MAY 23 PH 3- 04 UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA 9 10 CASE NO. 99-CV-2668 H (AJB) GEN-PROBE INCORPORATED. 11 Plaintiff, JÜÜGMENT FOR GEN-PROBE 12 RATORY ACTION OF 13 14 15 VYSIS, INC., 16 Defendant. 17 This action came before the Court for a trial by jury on May 7, 2002. The issues have been 18 tried and the jury has rendered the following special verdict on May 22, 2002: 19 INFRINCEMENT 20 Has Vysis, Inc. ("Vysis") proved by a preponderance of the evidence that Gen Probe 21 Incorporated ("Gen-Probe") infringes the '338 patent under the doctrine of equivalents? 22 The Jury answered: No. 23 Identify any claims of the '338 patent that Vysis has proved are infringed under the 24 doctrine of equivalents: The Jury answered: Not applicable. 26 1111 27 1111 28 ENTERED ON 5-2308

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Has Gen-Probe proved by clear and convincing evidence that any or all of the claims of the '338 patent are invalid on the ground of obviousness?

The Jury answered: Yes.

Identify any claims of the '338 patent that Gen-Probe has proved are invalid on the ground of obviousness:

The Jury answered: All

5. Has Gen-Probe proved by clear and convincing evidence that any or all of the claims of the 338 patent are invalid on the ground of lack of enablement?

The Jury answeredt Yes.

Identify any claims of the '338 patent that Gen-Probe has proved are invalid on the ó. ground of lack of enablement:

The Jury poswered: All.

Has Gen-Probe proved by clear and convincing evidence that Vysis abandoned the Invention claimed in the '338 patent?

The Jury answered: No.

C. INEQUITABLE CONDUCT

Has Gen-Probe proved by clear and convincing evidence that Vysis misrepresented or failed to disclose material facts to the United States Patent and Trademark Office ("PTO") with the intent to deceive the PTO?

The Jury snawered: Yes,

9. Has Gen-Probe proved by clear and convincing evidence that Vysis deliberately and unreasonably delayed the prosecution of the '338 patent?

The Jury snswered: Yes.

In accordance with the Special Verdict filed on May 22, 2002, JUDGMENT IS ENTERED AS FOLLOWS:

As to infringement, judgment shall enter in favor of Gen-Probe Incorporated on its declaratory action of non-infringement of the United States Patent No. 5,750,338.

As to invalidity, judgment shall enter in favor of Gen-Probe Incorporated on its declaratory action of invalidity of United States Patent No. 5,750,338 based on obviousness and lack of enablement.

Because the jury verdict was advisory on the issues of unenforceability, the Court submits the judgment on inequitable conduct and prosecution laches.

IT IS ORDERED AND ADJUDGED.

DATED: 5/23/67

MARILYN II. HUFF, Chicf Marie UNITED STATES DISTRICT COURT

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THE PROPERTY OF THE PROPERTY O

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

CASE NO. 99-CV-2668 H (AJB)

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YYSIS, INC.,

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Defendant.

ORDER (1) DENYING GEN-PROBE INCORPORATED AND VYSIS, INC.'S PRE-VERDICT MOTIONS FOR JUDGMENT AS A MATTER OF LAW, AND (2). SETTING BRIEFING SCHEDULE FOR POST-TRIAL MOTIONS

Gen-Probe Incorporated ("Gen-Probe") has filed a declaratory judgment action against Vysis, Inc. ("Vysis"). The trial in this case commenced on May 7, 2002. During the trial, both Gen-Probe and Vysis filed motions for judgment as a matter of law under Federal Rule of Civil Procedure 50(a). Federal Rule of Civil Procedure 50(a) states in relevant part:

If during a trial by jury a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue, the coun may determine the issue against that party and may grant a motion for judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue

Fed. R. Civ. P. 50(a)(1). At the close of the evidence and all other appropriate times, the Court submitted the motions.

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The jury returned its special verdict on May 22, 2002. The jury found that the patent-in-suit was not infringed, was invalid based on obviousness and lack of enablement, and was unenforceable based on inequitable conduct and prosecution laches.

Having considered the evidence and the papers submitted to the Court in support of these pending motions, the Court denies all pending motions for judgment as a matter of law under Federal Rule of Civil Procedure 50(a).

The Court deems that the parties have renewed a motion for judgment as a matter of law after trial and have made a motion for new trial under Federal Rule of Civil Procedure 50(b). To address those post-inal motions, the Court sets the following briefing and hearing schedule:

- The parties' memorandium of contentions and facts in support of their renewed motions for judgment as a matter of law, along with the supporting lodgments, shall be filed and served no later than Monday June 17, 2002. The opposition papers shall be filed and served no later than Monday July 1, 2007. The reply papers shall be filed and served no later than Tuesday July 9, 2002.
- The hearing on the post-trial motions is scheduled for Monday July 22, 2002, at 10:30 a.m. (2) Unless otherwise notified by the Court, these motions are submitted on the papers without a hearing pursuant to Civ. L. R. 7.1(d)(1).
- Unless modified by this order, the parties shall comply with all the provisions of the Civil Local Rules, including Civ. L. R. 7.1(b).

IT IS SO ORDERED. 19

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Phone No.: 703-305-0761 # Pages (incl. this): 13
Subject: Reissue Appln of Collins et al. Date: June 11, 2002

Your File No.: Appln No. 09/533,906 Our File No.: 01147-0142

Confirmation Copy to Follow: No

Examiner Johannsen:

As we discussed, attached is the Updated Notice of Related Litigation, enclosing the

following:

- Transcript of Jury Verdict, May 22, 2002;
- Judgment for Gen-Probe on its Declaratory Action of Non-infringement and Invalidity; and
- Order (1) Denying Gen-Probe's and Vysis's Pre-Verdict Motions for Judgment as a Matter of Law, and (2) Setting Briefing Schedule for Post-Trial Motions.

Thank you again for your willingness to consider this submission.

Jean Fordis

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